ABSTRACT

Background:
Many factors play a role in determining whether a pathogen or toxin can be used successfully as a biological weapon by terrorists. Despite the relatively long list of agents regulated by the United States ("select agents"), only a relatively small subset can be used as a biological weapon to create a high consequence event. We believe that civilian preparedness, nonproliferation, and biodefense efforts should focus on those agents with the greatest risk of being used in bioterrorism incidents. A repeatable and defensible methodology is a necessary first step in prioritizing biological threat agents.

Methods:
We have developed a methodology for such prioritization through open literature surveys, subject matter expert consultations, and work with government entities. Weaponization potential includes such factors as the availability of a suitable strain, ease of production (an appropriate quantity in an appropriate form), modes of dissemination, hardiness of the agent (both in the laboratory and after deployment), and accessibility to the knowledge required to use the agent as a weapon. Potential consequences of use involve factors such as infectious dose, incubation period, pathogenicity, availability of preventive measures and/or post-exposure treatments, and modes and ease of transmission.

Results:
This prioritization of biological threat agents is based upon both the agents' weaponization potential and the consequences of their use. The resultant ranking may be used as input into both the policy making and overall risk assessment processes used domestically and internationally.

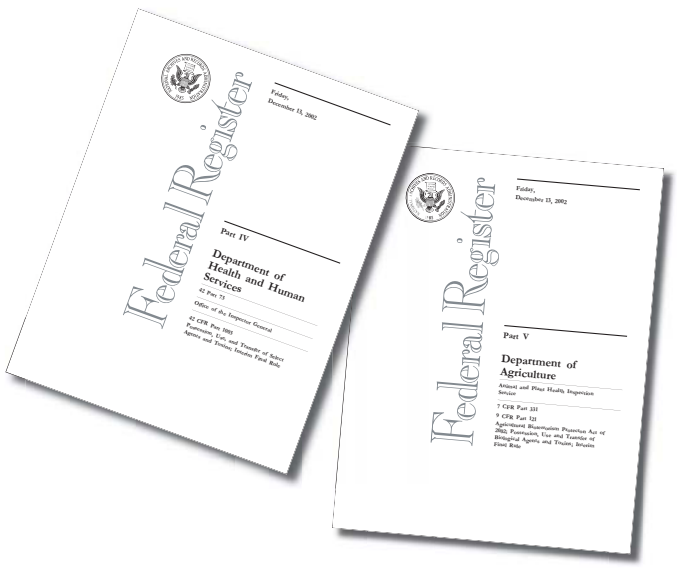
Conclusions:
As a test of the methodology, we will present a preliminary analysis of some of the select agents. This analysis will demonstrate that not all of the regulated agents present an equal risk and that using biosafety and regulatory requirements alone as a means of determining the level of protection a biological threat agent requires will lead to an inappropriate allocation of resources.

BACKGROUND

Current lists of biological threat agents are inadequate:

- World Health Organization – Public Health Response to Chemical and Biological Weapons provides descriptions of 19 pathogens and toxins
- CDC Category A, B, and C agents – exclusively human pathogens, focused on potential for greatest public health impact, little attention paid to how easy or difficult it would be to deploy an agent
- Select Agent lists - Very few of the 82 agents can be easily and successfully deployed as mass-casualty weapons

Problem: Control of certain biological materials is necessary but which materials are controlled and how that control is achieved must be carefully considered and implemented



A METHODOLOGY FOR PRIORITIZING BIOLOGICAL THREAT AGENTS

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RISK METHODOLOGY

Risk = Probability x Consequences

- Consequences: Maximum credible consequences of malicious use of agent
- Probability: difficult to impossible to measure; use threat potential as a proxy
  - Key assumption: Likelihood that an adversary will choose an agent depends on the likelihood that an agent can be successfully deployed
- Risk will always exist: every asset cannot be protected against every threat
  - Risk management approach
  - Distinguish between "acceptable" and "unacceptable" risks

Weaponization Potential attributes:

- Availability
- Ease of production
- Ease of handling
- Ease of packaging
- Modes of dissemination
- Stability

Consequence attributes:

- Contagiousness
- Genetic engineering
- Incubation period
- Medical effects (Morbidity and Mortality)
- Economic impacts
- Potential to become endemic

To fully assess the risk, the adversary must be considered. Threat potential consists of adversary potential and weaponization potential. There's a general lack of info about the adversary, any available information should be used to modify risk determined from an agent evaluation.

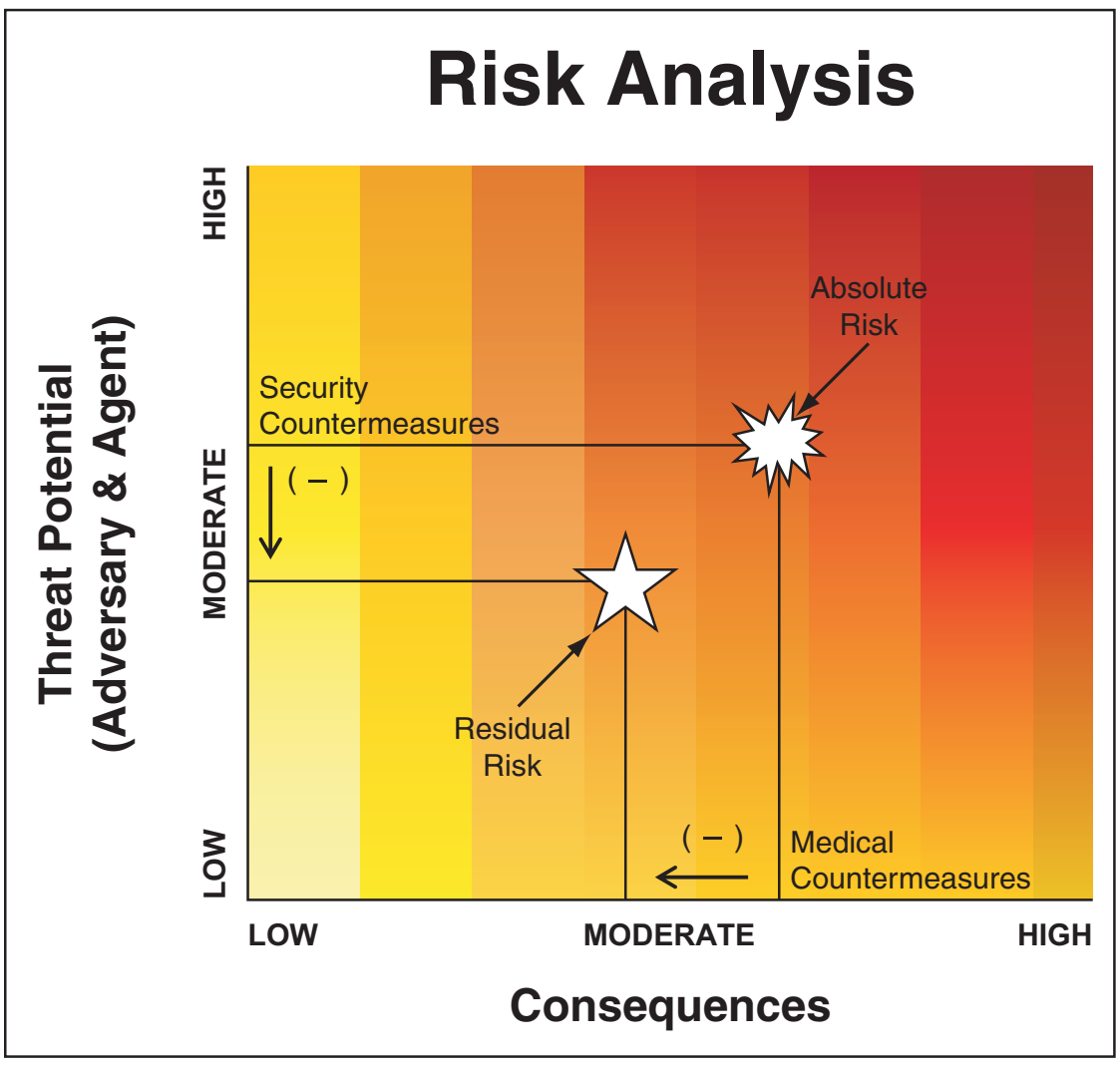
Risk Mitigation:
Risk can be reduced but not eliminated.
Risk can be mitigated by applying countermeasures against the threat and the consequences: remaining risk is the residual risk

Threat mitigation measures:

- Reduce adversary presence
- Reduce adversary motivation
- Reduce adversary opportunity (i.e. enhance security)
  - Personnel security
  - Physical security
  - Material control & accountability
  - Transport security
  - Information security

Consequence mitigation measures:

- Detection
- Decontamination
- Diagnosis
- Medical countermeasures
  - Pre and post exposure



EXAMPLE RISK ANALYSIS

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EBOLA VIRUS

General info:
RNA viruses that are encapsulated by a lipid membrane. Their genomes tend to range from about 10 kbps (kilo base pairs) to 19 kbps. Ebola and Marburg viruses are the only known members of the Filoviridae
Category A and Select agent

Weaponization potential:
Acquisition could be difficult – BSL 4 facilities, unknown natural reservoir (in Africa) – Synthesis of virus possible but extremely difficult
Egg and cell culture traditional methods of amplification but also grows to high titer in animal hosts
Moderate aerosol stability

Consequences:
ID_{50} low – presumed to be 1 – 10 virion particles
Incubation period: 2 – 21 days
High morbidity and mortality
Ebola mortality: 50 – 90%
Person to person transmission generally req. contact with bodily fluids; a very few instances of possible aerosol transmission.
Outbreaks have been self-limiting
Potential for public panic

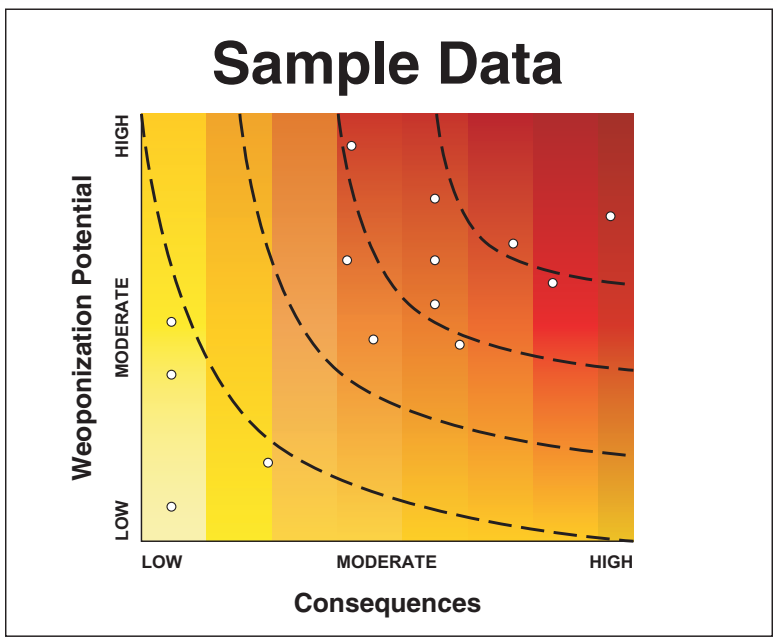
Consequence mitigation:
Supportive care only
Decontamination unlikely to be necessary

BRUCELLA SUIS

General info:
Select agent and Category B agent
gram-negative coccobacilli

Weaponization potential:
Brucellosis is pandemic (except UK and Australia); prevalence is higher in countries not requiring pasteurization of dairy products, especially Mediterranean Europe, the Middle East, and parts of South America

Wild mammals such as elk, bison, and wild boar serve as reservoirs for Brucella organisms



Brucella organisms can survive in tap water for several months. Brucella can survive in feces, slurry, or liquid manure 30 – 210 days. They can survive freezing temperatures and high environmental temperatures. Desiccation greatly reduces survival of brucellae

Most commonly lab-acquired infection; Brucella organisms can become airborne during standard laboratory procedures.

Consequences:
Brucellosis has fairly low fatality rate, but could be used as an incapacitating agent, as the disease tends to be chronic, requiring prolonged treatment

10 – 500 organisms in aerosol form constitute an infectious dose

Incubation period: 3 – 60 days

Consequence mitigation:
Antibiotic treatment (6 weeks); Relapses occur in 5% of patients due to sequestered organisms

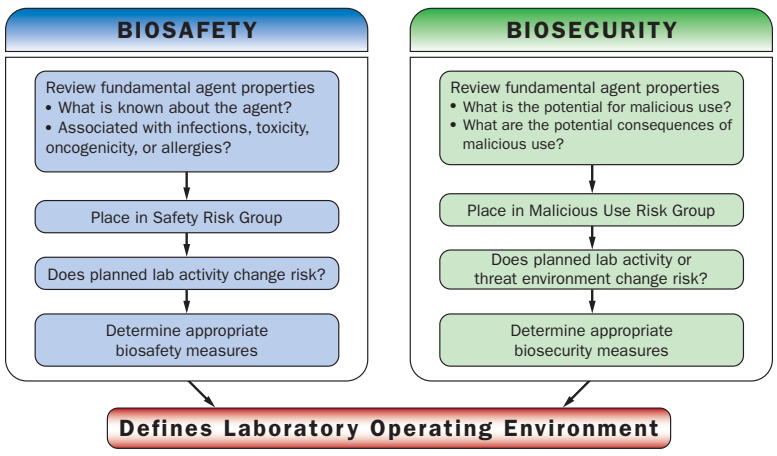
Live vaccine available for animals but not suitable for humans

Slaughter of infected animals

CONCLUSIONS

Not all Select Agents pose an equal risk from a bioterrorism perspective; risk assessment in necessary to determine appropriate resource allocation for future risk mitigation efforts (e.g. security, biodefense).

Biosecurity should be applied in a graded manner, ensuring that the amount of protection provided to a specific agent is proportional to the risk of the theft or sabotage of that agent.



Critical that biosecurity systems are designed specifically for biological materials and research so that the resulting system will balance science and security concerns.

In the laboratory, safety and security must coexist. We advocate the following model for using risk assessment to determine the laboratory operating environment:

ACKNOWLEDGEMENTS

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